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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,044	06/08/2000	TAEKYU LEE	TSR1609.1	2188

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,044

Applicant(s)

LEE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 6-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,6-9 and 18-22 is/are allowed.
- 6) ☒ Claim(s) 1,10 and 12-15 is/are rejected.
- 7) ☒ Claim(s) 11, 16, and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. The marked-up copy of amended claim 1 does not correspond with claim 1 as presented in the amendment filed June 28, 2001. In particular, the marked-up copy of amended claim 1 shows the deletion of the phrase "carbobenzyloxy-valine-," from the definition of R₁, which phrase does not occur in claim 1 as presented in the amendment filed June 28, 2001. Further, the marked-up copy of amended claim 1, last line, corrected the spelling of "nor" without marking the correction using underlining and bracketing. Any future amendments to the claims should be carefully reviewed to ensure full and accurate compliance with 37 CFR 1.121.

The structure set forth in claim 3 is illegible, possibly because of difficulties in the fax transmission. In their next response, Applicants are requested to attempt to re-submit a more legible copy of the claim, or else to give the examiner permission to insert a legible copy of the structure into the claim when this application passes to issue.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the Tam et al article. The Tam et al article teaches compound 3 (see Table I) which corresponds to Applicants' compounds of claim 1 in which R₁ is carbobenzoxy, R₂ is CH₂-Phenyl, and R₄ is -H(t-Butyl).

4. Claims 10 and 12-15 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application '948. The WO Patent Application '948 teaches compounds 9 and 108 (see pages 32 and 33) which differ from Applicants' claimed compounds of claims 10 and 12-15 in the substitution of valine or leucine residues for the alanine residues. The WO Patent Application '948 teaches in general that Ala, Leu, and Val can be used in these sections of the compounds, designated by the reference as (B)_n (see page 3, lines 1-8). It would have been

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obvious to one of ordinary skill in the art at the time Applicants' invention was made to form compounds according to the WO Patent Application '948 which have the structure of compounds 9 and 108 except that Leu or Val rather than Ala is present in the first and last and/or the second and second-to-last positions of each compound, because such compounds are generically embraced by the WO Patent Application '948, because the substitution of leucine or valine for alanine is a conservative substitution of amino acids and a homologous substitution of amino acid sidechains which would not have been expected to materially affect the activity of the compounds, and because the resultant compounds have only the HIV protease inhibitory activity which would have been expected in view of the WO Patent Application '948 (see, e.g., page 31). The WO Patent Application '948's compounds have the same stereochemistry required by Applicants' claims, although the WO Patent Application '948 does not teach the compounds in stereochemically pure form. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to form the stereochemically pure compounds of the WO Patent Application '948 as discussed above because it is desirable in the pharmaceutical arts to produce optically pure forms in order to avoid unwanted side effects from the other stereochemical forms and in order to increase the specific activity of the desired stereochemical forms, and because it is prima facie obvious to purify a known product. See MPEP 2144.04(VII).

5. Applicant's arguments filed May 29, 2002 have been fully considered but they are not persuasive.

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The rejection of claim 1 over the Tam et al article is maintained. Compound 3 of the Tam et al article does not contain a hydroxyl group which would trigger the proviso which is present in Applicants' claim.

The rejection over the WO Patent Application '948 is maintained. Applicants have not submitted a probative side-by-side comparison, commensurate in scope with the rejected claims, of Applicants' claimed compounds with the closest prior art of record. In particular, the K_i values reported in Applicants' specification and in the reference can not be relied upon to establish unexpected results because it has not been established that the same HIV-1 protease was used under the same reaction conditions. Unless the reaction conditions and reagents are fixed, it can not be concluded that a difference in the K_i is a result of a difference in the structure of the inhibitors. Further, Applicants did not provide any comparative testing involving the compounds claimed in instant claims 13-15, which necessarily includes determining the K_i for compound 108 of the reference. In general, see MPEP 716-716.02(g) concerning the demonstration of unexpected results under 37 CFR 1.132.

6. Claims 3, 6-9, and 18-22 are allowed. Claims 11, 16, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

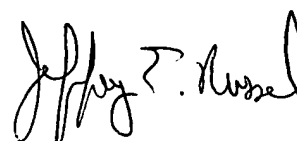
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel

July 2, 2002